UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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ENDO PHARMACEUTICALS INC. and
GRÜNENTHAL GMBH,

Plaintiffs,

-against-

TEVA PHARMACEUTICALS USA, INC.
and BARR LABORATORIES, INC.

Defendants.
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12-cv-8060 (TPG)

AMENDED JUDGMENT

Whereas the above-captioned actions having come before this Court, and on April 24, 2015 marked the conclusion of a five-week bench trial for patent infringement; Plaintiffs Endo Pharmaceuticals Inc. ("Endo") and Grünenthal GmbH ("Grünenthal") argue that defendants, Teva Pharmaceuticals USA, Inc., and Barr Laboratories, Inc. (collectively "Teva" or "Defendants"), which are generic drug manufacturers, infringe on patents covering Endo's branded painkiller OPANA® ER by selling or seeking approval to sell generic versions of the drug; Defendants argue that their generic products, as described in their abbreviated New Drug Applications ("ANDAs"), do not and will not infringe the asserted claims of the patents asserted against Defendants, and that in any event those patents are invalid; there are a total of three patents-in-suit; Endo owns two of the patents asserted against all Defendants, United States patent numbers 8,309,122 ("the '122 Patent") and 8,329,216 ("the '216 Patent"), which recite a controlled release formulation of the painkilling opioid oxymorphone

suitable for twelve-hour dosing; Grünenthal owns the third patent, United States Patent Number 8,309,060 ("the '060 Patent"), which describes an invention for drug-tablets so hard that they are difficult to abuse through crushing and snorting, and which also accommodate other barriers to abuse; and the matter having come before the Honorable Thomas P. Griesa, United States District Judge, and the Court, on August 14, 2015, having rendered its Findings of Fact and Conclusions of Law the Court concluding that all Defendants' generic products, as described in their ANDAs, infringe all but two of the asserted claims of the '122 and '216 patents, and that Defendants having failed to satisfy their burden of showing those claims to be invalid; the Court concluding that Defendants infringe the asserted claims of the '060 Patent, but that they have satisfied their burden and shown those claims to be invalid based on obviousness, but have not satisfied their burden of showing that those claims are invalid on any other grounds, including under the provisions of 35 U.S.C. §§ 101, 102, and 112, and have not satisfied their burden of showing that the asserted claims of the '060 patent are invalid based on collateral estoppel; and for the reasons set forth with respect to co-defendant Roxane Laboratories Inc., in the Court's subsequent April 29, 2016 Omnibus Opinion and the Court's Order Resolving Post-Trial Motions, the Court entering judgment in Endo's favor and permanently enjoining Defendants from making or selling their generic products prior to the expiration of the '122 and '216 patents pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283; moreover, the Court ordering that the effective date of approval of defendants' ANDAs shall be no

sooner than the expiration date of the '122 and '216 patents pursuant to 35 U.S.C. §271(e)(4)(A); and the Court now having resolved all pending motions in the above-captioned case via its Order Resolving Post-Trial Motions (which is being entered in conjunction herewith), it is,

ORDERED, ADJUDGED AND DECREED: That for the reasons stated in the Court's Findings of Fact and Conclusions of Law dated August 14, 2015, the Court's subsequent April 29, 2016 Omnibus Opinion and the Court's Order Resolving Post-Trial Motions, that Defendants' generic products, as described in their ANDAs, infringe all but two of the asserted claims of the '122 and '216 patents, and that Defendants have failed to satisfy their burden of showing those claims to be invalid; that Defendants infringe the asserted claims of the '060 Patent, but that they have satisfied their burden and shown those claims to be invalid based on obviousness; judgment is hereby entered in Endo's favor and enjoining Defendants pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 from the manufacture, use, offer to sell, or sale within the United States or importation into the United States of their generic products prior to the expiration of the '122 and '216 patents, said injunctive relief shall not cover any activities that are protected by the "safe harbor" provision of 35 U.S.C. § 271(e)(1); moreover, the Court orders pursuant to 35 U.S.C. §271(e)(4)(A) that the effective date of approval of defendants' ANDAs shall be no sooner than the expiration date of the '122 and '216 patents; with respect to Defendants' counterclaims against the asserted claims of the '122 and '216 patents, judgment is hereby entered in Endo's favor on all counterclaims, except with

respect to the counterclaims of non-infringement of the '216 patent as they relate to claims 40 and 42, as to which judgment is entered in Defendants' favor, and with respect to the counterclaims of invalidity of the '216 patent as they relate to claims 40 and 42, which are dismissed as moot; with respect to Defendants' counterclaims against the asserted claims of the '060 patent, judgment is hereby entered in Endo's and Grünenthal's favor on all counterclaims of non-infringement, in Defendants' favor on their counterclaims of invalidity based solely on obviousness but not on any other invalidity grounds, and in Endo's and Grünenthal's favor on all counterclaims of invalidity of the asserted claims of the '060 patent based on the provisions of 35 U.S.C. §§ 101, 102, and 112; the Court also rules in Endo's and Grünenthal's favor that the OxyContin invalidity decision regarding asserted claims of the '383 patent has no preclusive effect on the asserted claims of the '060 patent.

SO ORDERED

Dated: New York, New York
June 29, 2016

Thomas P. Griesa
U.S. District Judge